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PTO/SB/21 (09-04)

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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

8

Application Number	10/607,446
Filing Date	06/25/2003
First Named Inventor	Vinayak Sant
Art Unit	1632
Examiner Name	

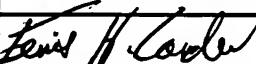
Attorney Docket Number

2267.005

### ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
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<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		
Remarks		

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	McHale & Slavin, P.A.		
Signature			
Printed name	Ferris H. Lander		
Date	2/14/2005	Reg. No.	43,377

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICANT : Vinayak Sant et al  
INVENTION : pH-SENSITIVE BLOCK COPOLYMERS FOR  
SERIAL NUMBER : 10/607,446  
FILING DATE : June 25, 2003  
EXAMINER :  
GROUP ART UNIT : 1632  
ATTORNEY DOCKET NO. : 2267.005



CERTIFICATE UNDER 37 CFR §1.8(a)  
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**INFORMATION DISCLOSURE STATEMENT**

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Alexandria, VA 22313-1450

Sir:

Pursuant to the duty of disclosure under 37 CFR §1.56, the references cited on the accompanying forms PTO/SB/08A and PTO/SB/08B are hereby brought to the attention of the Examiner for independent evaluation. The references cited herein have been made of record in parent U. S. Patent Application No. 09/877,999, filed June 8, 2001, upon which the present application claims priority under 35 USC §120. Therefore, pursuant to 37 CFR §1.98(d), Applicants are not required to submit copies of the cited references. Copies of those cited references not previously provided and/or cited in the parent application are enclosed herewith.

Applicants submit that the present invention is patentable over the cited references.

Respectfully submitted,

Date

2/14/2005

By

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PTO/SB/08A (08-03)

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Substitute for form 1449/PTO

**Complete if Known****INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

1

of

5

Application Number	10/607,446
Filing Date	06/25/2003
First Named Inventor	Vinayak Sant
Art Unit	1632
Examiner Name	

Attorney Docket Number 2267.005

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 5,620,850	04/15/1997	Bamdad et al	
		US- 5,908,777	06/01/1999	Lee et al	
		US- 5,770,627	06/23/1998	Inoue et al	
		US- 5,955,509	09/21/1999	Webber et al	
		US- 5,693,751	12/02/1997	Sakurai et al	
		US- 5,702,717	12/30/1997	Cha et al	
		US- 5,939,453	08/17/1999	Heller et al	
		US- 5,786,387	07/28/1998	Watanabe et al	
		US- 5,510,103	04/23/1996	Yokoyama et al	
		US- 6,372,203	04/16/2002	Allwohn et al	
		US- 6,440,743	08/27/2002	Kabanov et al	
		US- 6,221,959	04/24/2001	Kabanov et al	
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		US- 5,925,720	07/20/1999	Kataoka et al	
		US- 5,929,177	07/27/1999	Kataoka et al	
		US- 5,840,319	11/24/1998	Alakhov et al	
		US- 2002/0187199A1	12/12/2002	Ranger et al	
		US- 6,491,901	12/10/2002	Gers-Barlag et al	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
		EP 0963758	12/15/1999	Universiteit Gent		
		WO96/21036	07/11/1996	Chiron Viagene, Inc.		
		WO96/32841	10/24/1996	Burstein Laboratories, Inc.		
		WO98/19710	05/14/1998	E. Schacht et al		
		WO97/33737	09/18/1997	President and Fellows of Harvard College		
		WO98/37902	09/03/1998	The Regents of the University of California		

Examiner Signature		Date Considered	
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**Substitute for form 1449/PTO**

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

*(Use as many sheets as necessary)*

Sheet 2 of 5

**Complete if Known**

Application Number	10/607,446
Filing Date	06/25/2003
First Named Inventor	Vinayak Sant
Art Unit	1632
Examiner Name	
Attorney Docket Number	2267.005

**U. S. PATENT DOCUMENTS**

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>8</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		WO01/87227	11/22/2001	Labopharm, Inc.		
		WO2004/035013	04/29/2004	L'oreal		

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				Filing Date	06/25/2003
				First Named Inventor	Vinayak Sant
				Art Unit	1632
				Examiner Name	
Sheet	3	of	5	Attorney Docket Number	2267.005

<b>NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		B. LELE et al, "Mucoadhesive drug carriers based on complexes of poly(acrylic acid) and PEGylated drugs having hydrolysable PEG-anhydride-drug linkages", Journal of Controlled Release, 69:237-248 (2000)	
		V. COESENNS et al, "Functional polymers by atom transfer radical polymerization", Prog. Polym. Sci., 26:337-377 (2001)	
		Y. KAKIZAWA et al, "Environment-sensitive stabilization of core-shell structured polyion complex micelle by reversible cross-linking of the core through disulfide bond", J. Am. Chem. Soc., 121:11247-11248 (1999)	
		K. KATAOKA et al, "Spontaneous formation of polyion complex micelles with narrow distribution from antisense oligonucleotide and cationic block copolymer in physiological saline", Macromolecules, 29:8556-8557 (1996)	
		SCHOLZ et al, "A novel reactive polymeric micelle with aldehyde groups on its surface", Macromolecules, 28:7295-7297 (1995)	
		LEE et al, "Synthesis and micellar characterization of amphiphilic diblock copolymers based on poly(2-ethyl-2-oxazoline) and aliphatic polyesters", Macromolecules, 32:1847-1852 (1999)	
		BENAHMED et al, "Novel polymeric micelles based on the amphiphilic diblock copolymer poly(N-vinyl-2-pyrrolidone)-block-poly(D,L-lactide)", Pharmaceut. Res., 18(3):323-328 (2001)	
		K. KATAOKA et al, "Doxorubicin-loaded poly(ethylene glycol)-poly(beta-benzyl-L-aspartate) copolymer micelles: their pharmaceutical characteristics and biological significance", Journal of Controlled Release, 64:143-153 (2000)	
		K. KATAOKA et al, "Design of nanoscopic vehicles for drug targeting based on micellization of amphiphilic block copolymers", J.M.S.-Pure Appl. Chem., A31(11):1759-1769 (1994)	
		L. ZHANG et al, "Multiple morphologies of "crew-cut" aggregates of polystyrene-b-poly(acrylic acid) block copolymers", Science, 268:1728-1731 (1995)	

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Sheet	4	of	5	Attorney Docket Number	2267.005

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		C. ALLEN et al, "Nano-engineering block copolymer aggregates for drug delivery", <i>Colloids and Surfaces b: Biointerfaces</i> , 16:1-24 (1999)	
		C-L. ZHAO et al, "Fluorescence probe techniques used to study micelle formation in water-soluble block copolymers", <i>Langmuir</i> , 6:514-516 (1990)	
		A. KABANOV et al, "The neuroleptic activity of haloperidol increases after its solubilization in surfactant micelles", <i>FEBS Letters</i> , 258(2):343-345 (1989)	
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		INOUE et al, "An AB block copolymer of oligo(methyl methacrylate) and poly(acrylic acid) for micellar delivery of hydrophobic drugs", <i>J. Controlled Release</i> , 51:221-229 (1998)	
		M. HELLER et al, "Co9nformational stability of lyophilized PEGylated proteins in a phase-separating system", <i>Journal of Pharmaceutical Sciences</i> , 88(1):58-64 (1999)	
		L. STRYER, in <i>Biochemistry</i> , Chapter 7, pp. 154-155, fourth edition, W. H. Freeman and Company, New York (1995)	
		M-C. JONES et al, "Polymeric micelles-a new generation of colloidal drug carriers", <i>European Journal of Pharmaceutics and Biopharmaceutics</i> , 48:101-111 (1999)	
		S. FULLERTON et al, "Molecular and population genetic analysis of allelic sequence diversity at the human beta-globin locus", <i>Proc. Natl. Acad. Sci. USA</i> , 91(5):1805-1809 (1994), (GenBank Accession No. AAA21101, published 8/6/1994 - retrieved from <a href="http://www.ncbi.nlm.nih.gov:80/entrez/viewer.fcgi?db=protein&amp;val=532507">http://www.ncbi.nlm.nih.gov:80/entrez/viewer.fcgi?db=protein&amp;val=532507</a> on 3/30/04)	
		S. LIEBHABER et al, "Cloning and complete nucleotide sequence of human 5'-alpha-globin gene", <i>Proc. Natl. Acad. Sci. USA</i> , 77(12):7054-7058 (1980), (GenBank Accession No. CAA23748 published 4/24/1993 - retrieved from <a href="http://www.ncbi.nlm.nih.gov:80/entrez/viewer.fcgi?db=protein&amp;val=51618">http://www.ncbi.nlm.nih.gov:80/entrez/viewer.fcgi?db=protein&amp;val=51618</a> on 3/30/04)	

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				<b>Filing Date</b>	06/25/2003
				<b>First Named Inventor</b>	Vinayak Sant
				<b>Art Unit</b>	1632
				<b>Examiner Name</b>	
Sheet	5	of	5	Attorney Docket Number	2267.005

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